

## REMARKS

In the Office Action dated November 13, 2006, claims 18, 20, 22-24, 26-30 and 32-34 were rejected and the rejection was made final. Applicant has carefully considered the Office Action and submits the amendments above and the remarks to follow as a full and complete response thereto. Further, Applicant submits that the amendments introduce no new matter, raise no new issues for examination and place the matter in condition for allowance or in better condition for appeal.

Applicant has amended the specification in response to the Examiner's comments and restructured the claims to place them within the metes and bounds of the corresponding EPO patent application which has been allowed. (Applicant notes that the amendments submitted in the previous response were not entered.)

Applicant has not accepted the invitation to amend the description of Fig. 2 since there is no sequence rule applicable to doxorubicin attached to a peptide, and the illustrated sequence cannot be entered as a sequence listing (37 CFR 1.821).

Applicant reaffirms the Remarks made in the previous Response.

Applicant augments those remarks to elucidate a difference between the reference WO 98/10794 cited by the Office and the invention claimed as herein (c.f. claim 35).

According to the Office, seven molecules of doxorubicin are linked per molecule of albumin. According to Applicant's claimed invention, the drug (eg. DOXO) binds exclusively via cysteine-34 of albumin. Cysteine-34 is the only cysteine residue available, amongst the 35 total, which is available for binding to the thiol group because the remaining 34 cysteine residues of albumin each

participate in cysteine-disulfide bonds. Only one drug molecule binds to one albumin at a time.

Applicant submits that the rejection of claims 18 (now 35), 20, 22-24, 26, 27 and 32-34 under 35 USC 102(b) has been traversed because the cited reference fails to disclose the medicament wherein the carrier drug is bound exclusively to cysteine-34 and whereby at least 0.7 mol of drug is bound per mole albumin at cystein-34. These are issues of both specificity and affinity not disclosed or even suggested by the reference.

With respect to the rejection of claims 33 and 34 under 35 USC 103(a) over WO 98/10794, the Office has presumed that Applicant is attempting to claim in kit form, Applicant refers to the Remarks made at pages 8 and 9 of the previous response. Furthermore, Applicant notes that the high specificity – 0.7 mol of drug moiety per mol of albumin- is highly advantageous in view of the low availability of free cysteine-34 residues in commercially available albumin. In most available grads, 80% of cysteine-34 residues are blocked by non-specific sulfides. This is not a kit including the medicament disclosed in the reference.

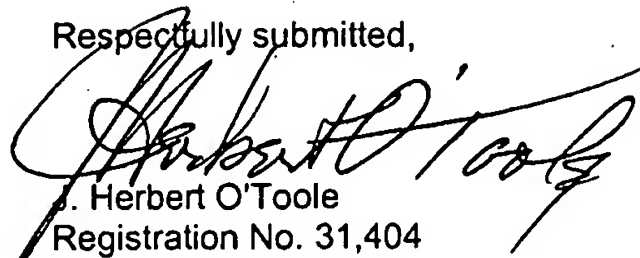
Further contrast may be found in the uniformity and purity of the claimed carrier-drug conjugate. The material of the cited reference consists of a mixture of albumins having 0 to 10 or more drug molecules associated therewith.

All claims were rejected under 35 USC 102 (a) over Kratz, J. Med. Chem. 43, 1253 (2000). The article was published March 10, 2000. Applicant's priority date is June 10, 1999 (DE 19926 475.9). The article is not a proper reference.

In view of the Amendments and Remarks *supra*, Applicant submits that this application is in condition for Allowance and requests reconsideration and favorable action thereon.

Applicant notes that this paper is filed within two months of the mailing  
date of the Final Rejection.

Respectfully submitted,



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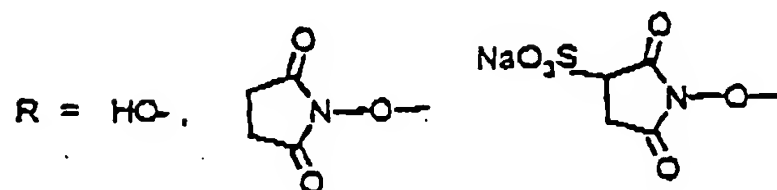
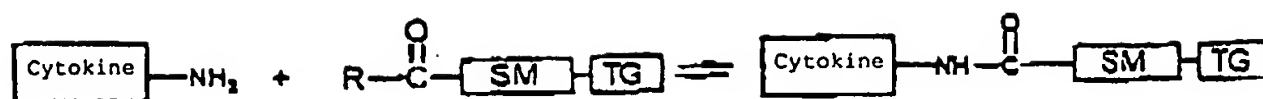
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Date:

January 16, 2007

by: Jacqueline Beavers





for example, by reacting the cytokine with a spacer molecule containing a thiol-binding group, which spacer molecule exhibits a carboxylic acid or an activated carboxylic acid: